

AMENDMENT AND RESPONSE UNDER 37 CFR 1.121
U.S.S.N. 09/442,256
Filed: November 17, 1999

REMARKS

2. PENDING CLAIMS AND SUPPORT FOR AMENDMENT

Upon entry of the present amendment, claims 4, 6, 8-9, 12-14, 22, 24-26, 29, 32, 36, 38-40, and 54-72 is pending in the application. Claim 5 is withdrawn without prejudice. Claims 4, 22, 29, 32, 39, 54, 55, 58, 67, and 69 have been amended to include more specific language concerning the extracts. Applicant respectfully submits that the amendments to these claims make them readable on the elected invention, and requests that the withdrawal of these claims be reconsidered.

3. REJECTIONS UNDER 35 U. S. C. 112:

“Claims 22, 29, 36 and 54 are rejected under 35 U. S. C. 112, as being the specification does not support the claimed subject matter with respect to the broad claimed solvent since the examples are only drawn to specific solvents.”

The applicant kindly requests approval of the amendments to claims. Such amendments specify the different solvents or a mixture of solvents as selected from the group consisting of methanol, hexane, ether, and acetone.

4. "Claims 22, 29, 54 stands rejected, under 35 U.S.C. 102(b) as anticipated by or, in alternative, under 35 U. S. C. 103(a) As obvious over Suffness et al NAPRALERT (Reference W)":

Suffness et al NAPRALERT (Reference W) Nature Product Branch, NCI, NIH, Bethesda MD. Whether, Suffness submitted *Hagenia abyssinica* to NCI/NIH as collaborative research effort or has done the test by his own is not clear. However, he teaches us Eth. 95% extract of *Hagenia abyssinica*. His work of "Leukemia compared to B16 Melanoma and Colon carcinoma" on the basis of qualitative results. He did not use different solvents nor did he screen broad based tumor cell lines. He did not indicate the Chemical composition or compound analysis from the *Hagenia abyssinica* using either new or an available method and applications.

Applicant respectfully traverses this rejection and requests reconsideration and withdrawal thereof.

Kokwaro NAPRALERT 92: 32733 (Reference X); He teaches us hot water extraction of *Hagenia abyssinica* for treating malaria. Also, extract of *Hagenia abyssinica* with Isopropanol - H₂O (1:1) has been indicated for treating to expel Tapeworm. Kokwaro did not show any new findings nor tested an extract of *Hagenia abyssinica* against cancer cell lines. His teaching does not establish scientific merit for rejection. He has not indicated GC/MS compound analysis. He has not used multiple organic solvent extractions. Moreover, he has not used the solvents specified in the amended claims. Applicant respectfully traverses this rejection and requests reconsideration and withdrawal thereof.

The Examiner stated on this section of rejection citing references: Ageel et al BIOS ABSTRACT BA89:92285, Kavimani et al CABA ABSTRACT 2000:53058 or Shah et al SCISEARCH

ABSTRACT 91: 548657. "Each of the reference teaches an organic solvent extract of *Hagenia abyssinica*. which anticipates the claimed inventions or render the claims obvious for the separation of the extract absent a showing of unexpected or unobvious process steps."

Neither Ageel et al, BIOS ABSTRACT BA89:92285, Kavimani et al CABA ABSTRACT 2000:53058 nor Shah et al SCISEARCH ABSTRACT 91: 548657 utilized organic solvents extract with *Hagenia abyssinica*; therefore there are no established bases for rejection. However, each of the above references teach us alternate plants other than *Hagenia abyssinica* and the applicant kindly responds to each on the section 5 rejection. Furthermore, the authors have not used multiple organic solvent extractions.

Applicant respectfully traverses this rejection and requests reconsideration and withdrawal thereof.

5. "claims 22, 29, 54 are rejected under 35 U. S. C. 103(a) as being obvious over Suffness et al NAPRALERT (Reference W) Ageel et al, Kavimani et al (CABA ABSTRACT 2000:53058) or Shah et al (SCISEARCH ABSTRACT 91:548657)".

Applicant respectfully traverses this rejection and requests reconsideration and withdrawal thereof.

The Examiner asserts that each of these references teaches the extraction of plant material with a solvent that is within the scope of the claimed process. The Examiner concedes, however, that these references do not disclose additional solvent extraction. Nevertheless, the Examiner considers it obvious to one of ordinary skill in the art to add additional solvent extraction steps to maximize separation and to increase yield absent some unexpected difference in result due to the second process step.

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As recognized by the Examiner, Suffness reference does not teach or suggest conducting multiple extractions with the solvent or conducting extractions with different or multiple solvents. The reference also does not teach or suggest adjusting the pH of the solution to help elute or disassociate any compounds from their natural state in the plant material. Suffness does not suggest or teach the use of *Glinus lotoides*, *Ruta chalepensis*, or *Millettia ferruginea*, or teach the use of solvents other than ethanol.

Kokwaro NAPRALERT 92: 32733 (Reference X); reference does not teach or suggest conducting multiple extractions with the solvent or conducting extractions with different or multiple solvents. The reference also does not teach or suggest adjusting the pH of the solution to help elute or disassociate any compounds from their natural state in the plant material. Kokwaro does not suggest or teach the use of *Glinus lotoides*, *Ruta chalepensis*, or *Millettia ferruginea*, or teach the use of solvents other than Isopropanol and water.

Ageel reference also does not teach or suggest adjusting the pH of the solution to help elute or disassociate any compounds from their natural state in the plant material or conducting multiple extractions with the solvent or conducting extractions with different or multiple solvents. Further, Ageel does not suggest or teach the use of *Glinuslotoides*, *Hagenia abyssinica*, or *Millettia ferruginea*, or teach the use of solvents other than ethanol.

Also recognized by the Examiner, the Kavimani reference does not teach or suggest conducting multiple extractions with the solvent or conducting extractions with different or multiple solvents.

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The reference also does not teach or suggest adjusting the pH of the solution to help elute or disassociate compounds from their natural state in the plant material. Further, Kavimani does not suggest or teach the use of *Ruta chalepensis*, *Hagenia abyssinica*, or *Millettia ferruginea*, or teach the use of multiple solvents other than methanol.

The Shah reference also fails to teach or suggest conducting multiple extractions with the solvent, conducting extractions with different or multiple solvents, or adjusting the pH of the solution to help elute or disassociate any different or unknowns from their natural state in the plant material. Further, Shah does not suggest or teach the use of *Glinus lotoides*, *Hagenia abyssinica*, or *Millettia ferruginea*, or teach the use of solvents other than ethanol.

The references cited do not suggest a single extraction of these plant materials, or multiple extractions, or pH adjustments as claimed by Applicant. Furthermore, Applicant's methods provide different compositions than those resulting from the extractions of the plant materials in the cited references. Applicant respectfully asserts that claim 22, 29, 36, 54 and the claims which depend therefrom are clearly allowable.

Additionally, as recognized by the Examiner, none of the references teach or suggest multiple extractions of any plant material, and none teach adjusting the pH of the composition. The Examiner has conceded that each reference describes only one extraction of the plant material, whereas Applicant claims multiple extractions. It cannot be considered obvious to one of ordinary skill in the art to perform multiple extractions when there is no such suggestion in the cited art. Nor can it be considered obvious to perform extractions with various or different solvents because, again, there

is no such teaching or suggestion in the cited art. On the other hand, the inventor has determined that multiple extractions often produce different peaks when the resulting compositions are run through Gas Chromatography/Mass Spectrometry ("GC/MS") as compared to compositions resulting from single extractions analyzed in this same way. This is not predictable or expected. Plants contain a variety of compounds that simply cannot be extracted out by using one solvent, and the GC/MS results obtained by Applicant confirm this.

When the inventor used multiple extractions, he was able to recover unknown or disassociated compounds that were not detectable after single extractions. Thus, by applying Applicant's method of multiple extractions, optionally using different solvents for different extractions, compositions containing compounds that previously had not been extracted or that experimenters were not aware even existed, were obtained. Applicant respectfully asks the Examiner for review of the above-described GC/MS results if the Examiner believes it would be helpful in advancing the prosecution of this application. However, Applicant does not believe that such results are necessary to patentability of the claimed compositions because, in Applicant's view, the Examiner has not established a *prima facie* case of obviousness. Furthermore, the cited art does not suggest a method for providing a plant extract composition by extracting the plant material and then adjusting the pH of the plant material or resulting crude material. Applicant has determined that altering the pH (to either a basic or an acidic pH or both) helps extract or disassociate compounds from their natural state in the plant material in such a way that provides GC/MS peaks that are not obtained when the pH is not adjusted. This method provides new ways to identify compounds present in the studied plant materials. The claimed method of multiple extractions and/or pH adjustment of the plant

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materials is not taught by the cited references, nor is it obvious to one of ordinary skill in the art.

6. **"NO CLAIM IS ALLOWED."**

"Will consider allowing claim 36 with the elected plant and organic solvent."

Applicant respectfully submits that the amendments to these claims make them readable on the elected invention, and requests that the claims with amendments be reconsidered.

Applicant respectfully traverses this rejection and requests reconsideration and withdrawal thereof

CONCLUSION

Because Applicant has provided a novel and non-obvious method to isolate and provide extracts of plant materials and to determine the active compounds in those plant materials, an early and favorable allowance of the pending claims is earnestly solicited.

Respectfully submitted,

Tesfaye Yigzaw 8/16/03

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